

ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash
CDMA

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Antiseptic Mouth Rinse 318.003/318AH-AI

Active ingredients

Eucalyptol 0.092%, Menthol 0.042%
Methyl salicylate 0.060%, Thymol 0.064%

Purpose

Antigingivitis, Antiplaque

Use

Helps control plaque that leads to gingivitis

Warnings

Do not use

if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist if

gingivitis, bleeding, or redness persists for more than 2 weeks

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then spit out

children under 12 years of age - consult a dentist or doctor

- do not swallow

- not intended to replace brushing or flossing

Other information

cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59° - 77°F)

Inactive ingredients

water, alcohol 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

disclaimer

This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Original Listerine Antiseptic Mouthwash

adverse reaction section

Distributed by C.D.M.A., Inc

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

Questions 800-935-2362

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Antiseptic

Mouth Rinse

Antigingivitis| Antiplaque

Kills Germs That Cause:

Bad Breath

Plaque


Gingivitis

Gum Disease

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1 L (33.8 FL OZ)

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Antigingivitis | Antiplaque

Kills Germs That Cause:
Bad Breath
Plaque
Gingivitis
Gum Disease

Original



1 L (33.8 FL OZ)

L0018912FA

ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-318
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/25/2019	

Labeler - CDMA (011920774)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63868-318)

Revised: 4/2021

CDMA